



06-16-06

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# CERTIFICATE OF MAILING

Inventors: Codd, et al  
Title of Invention: Bicifadine Formulation  
Serial No.: 10/621,435  
Filing Date: July 17, 2003  
Attorney Dkt. No.: DOVP-1-0901 (Formerly 2370-009-03)

## CERTIFICATE OF MAILING OR TRANSMISSION

Date of Deposit: June 14, 2006

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### Enclosures:

Transmittal – Information Disclosure Statement  
Information Disclosure Statement (31 Citations)  
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Codd, et al  
Title: **BICIFIDINE FORMULATION**  
Application No.: 10/621,435  
Filing Date: July 17, 2003  
Examiner/Unit: 1724  
Atty. Docket No.: DOVP-1-0901 (Formerly 2370-009-03)

CERTIFICATE OF MAILING OR TRANSMISSION

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Amanda J. Mach

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT  
UNDER 37 CFR § 1.97**

TO THE COMMISSIONER FOR PATENTS:

In compliance with the duty of disclosure under 37 CFR § 1.56, Applicants submit herewith patents, publications, or other information for consideration during the examination of this application.

In accordance with 37 CFR § 1.97, the filing of this Supplemental Information Disclosure Statement shall not be construed to mean that a search has been made nor that the information cited in the statement is or is considered to be "material" to patentability as defined in 37 CFR § 1.56(b).

No fees are believed to be due in connection with the filing of this Information Disclosure Statement. However, should any fees be deemed necessary, the Commissioner is hereby authorized to deduct any necessary fees from Deposit Account No. 50-1050.

For the sake of completeness, the undersigned would also like to bring the following pending unpublished provisional and non-provisional US patent applications to the attention of the Office:

<u>Type</u>	<u>App. No.</u>	<u>Filing Date</u>	<u>Docket No.</u>
USPA	11/445,950	June 2, 2006	DOVP-1-0404
USPA	11/438,909	May 22, 2006	DOVP-1-0904
USPA	11/433,789	May 12, 2006	DOVP-1-0607
USPA	11/433,790	May 12, 2006	DOVP-1-0403
USPA	11/384,219	March 17, 2006	DOVP-1-1202
USPA	11/371,178	March 7, 2006	DOVP-1-1903
USPA	11/263,045	October 31, 2005	DOVP-1-0101
USPA	11/260,887	October 26, 2005	DOVP-1-0902
USPA	11/254,242	October 18, 2005	DOVP-1-2001
USPA	11/205,956	August 16, 2005	DOVP-1-0502
USPA/PROV	60/703,364	July 27, 2005	DOVP-1-2101
USPA/PROV	60/702,800	July 26, 2005	DOVP-1-1801

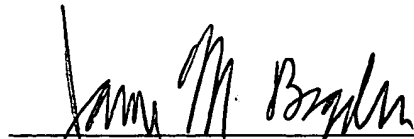
These pending applications are being brought to the attention of the Office since they are in a similar technical field as and share common ownership with the present application. These unpublished applications are being identified for the Office's attention only and are not intended or authorized to become part of the file wrapper of the present application. No representation is made that the foregoing unpublished applications are or are considered to be "material" to patentability as defined in 37 CFR § 1.56(b).

As provided in 37 CFR § 1.98, only copies of foreign patent documents and non-patent literature documents cited in the attached PTO SB-8a and 8b are attached.

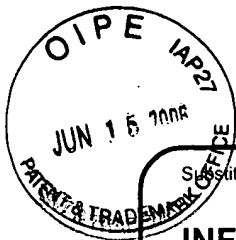
Date: June 14, 2006

Respectfully submitted,

**BLACK LOWE & GRAHAM PLLC**

A handwritten signature in black ink, appearing to read "James M. Bogden", is written over a horizontal line.

James M. Bogden, Esq.  
Attorney for Applicant  
Registration No. 32,962  
701 Fifth Avenue – Suite 4800  
Seattle, WA 98104  
Telephone: (206) 381-3300  
Facsimile: (206) 381-3301



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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet 1 Of 4

**Complete if Known**

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First Named Inventor	Codd, et al.
Art Unit	1724
Examiner Name	N/A
Attorney Docket Number	DOVP-1-0901

**U.S. PATENT DOCUMENTS**

Exam. Initials	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code <sup>2</sup> (if known)			
	AA	US- 4,022,652	05/10/77	Hirano, et al	
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	AR	US- 5,556,838	09/17/96	Mayer, et al	
	AS	US- 5,574,052	11/12/96	Rose, et al	
	AT	US- 5,969,156	10/19/99	Briggs, et al	
	AU	US- 5,985,864	11/16/99	Imai, et al	
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	BH	USSN 10/764,373 2004-0157870	08/12/04	Lippa, et al	
	BI	USSN 10/764,375 2004-0157908	08/12/04	Lippa, et al	
	BJ	USSN 10/702,397 2004-01002638	05/27/04	Russell, et al	
	BK	USSN 10/466,457 2004-0127541	07/08/04	Lippa, et al.	

FOREIGN PATENT DOCUMENTS							
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		Country Code <sup>3</sup> - Number <sup>4</sup> - Kind Code <sup>5</sup> (if known)					
	BL	BE 858,683		12/30/82	BE (In French w/English Abstract)		
	BM	BE 893,707		12/30/82	BE (In French w/English Abstract)		
Examiner Signature					Date Considered		

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STATEMENT BY APPLICANT**

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Sheet 3

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4

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Filing Date	July 17, 2003
First Named Inventor	Codd, et al.
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**NON PATENT LITERATURE DOCUMENTS**

Exam. Initials	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	BN	BALDESSARINI, R. <u>Drugs and The Treatment of Psychiatric Disorders</u> . Goodman & Gilman's The Pharmacological Basis of Therapeutics 9 <sup>th</sup> Edition. Hardman et al. eds. 1996. p. 399 and Ch 18:431-459, McGraw-Hill, New York	
	BO	BAYES, et al., Gateways to clinical trials - Allosteric Interaction Between The Site Labeled By [3H]imipramine And The Serotonin Transporter In Human Platelets. The oral analgesic activity of 1-aryl-3-azabicyclo[3.1.0]hexanes 1-aryl-3-azabicyclo[3.1.0]hexanes, a new series of non-narcotic analgesic agents. Methods Find Exp. Clin. Pharmacol. Apr Feb May 2003; 25(3):225-248.	
	BP	BLUM, et al., <u>Dopamine D2 Receptor Gene Variants: Association and Linkage Studies In Impulsive-Addictive-Compulsive Behavior</u> . Pharmacogenetics 5:121-141, 1996.	
	BQ	BRAY, G. <u>A Concise Review On The Therapeutics of Obesity</u> . Nutrition 16:953-960, 2000.	
	BR	CROWN, W. <u>Economic Outcomes Associated With Tricyclic Antidepressant And Selective Serotonin Reuptake Inhibitor Treatments For Depression</u> . Acta Psychiatr. Supp. 2000; 403:62-6.	
	BS	CZOBOR, P. <u>A Double-Blind, Placebo Controlled Randomized Study of DOV 220,075 (Bicifadine) SR and Codeine 60 mg in The Treatment of Post-Operative Dental Pain</u> . Abstract (915). American Pain Society (2003).	
	BT	D'AQUILA, et al, <u>The Role Of Dopamine In The Mechanism of Action of Antidepressant Drugs</u> . Eur. J. Pharmacol. 405:365-373, 2000.	
	BU	EPSTEIN, et al., <u>1-ARYL-3-AZABICYCLO[3.1.0]HEXANES, A New Series of Non-Narcotic Analgesic Agents</u> . J. Med. Chem. 24(5):481-90, 1981.	
	BV	FRAZER, A. <u>Norepinephrine Involvement In Antidepressant Action</u> . J. Clin. Psychiatry. 61(10):25-30, 2000.	
	BW	FREDMAN, et al., <u>Partial Response, Nonresponse, and Relapse With Selective Serotonin Reuptake Inhibitors In Major Depression: A Survey of Current "Next-Step" Practices</u> . J. Clin. Psychiatry 61(6):403-8, 2000.	
	BX	HACKH's Chemical Dictionary, 4 <sup>th</sup> Edition, 1969, Julius Grant, ed., McGraw-Hill Book Company, New York, pp. 474-75	
	BY	HARRISON's Principles of Internal Medicine 2485-2503 (Fauci, et al., eds., 14 <sup>th</sup> ed. 1998)	
	BZ	HITRI, et al., <u>Molecular, Functional and Biochemical Characteristics of The Dopamine Transporter: Regional Differences and Clinical Relevance</u> . J. Clin. Pharmacol. 17:1-22, 1994.	

CA	HOFFMAN, et al., <u>Localization and Dynamic Regulation of Biogenic Amine Transporters In The Mammalian Central Nervous System</u> . Front. In Neuroendocrinol. 19(3): 187-213, 1998.	
CB	KIYATKIN, E. <u>Dopamine Mechanisms of Cocaine Addition</u> . Int. J. Neurosci. 78:75-101, 1994.	
CC	KREEK, M. <u>Cocaine, Dopamine and The Endogenous Opioid System</u> . J. Addict. Dis. 15:73-96, 1996.	
CD	LEONHARDT, et al., <u>New Approaches In The Pharmacological Treatment of Obesity</u> . Eur. J. Nutr. 38:1-13, 1999.	
CE	MEYERSON, et al., <u>Allosteric Interaction Between The Site Labeled by [3H]imipramine and The Serotonin Transporter In Human Platelets</u> . J. Neurochem. 48(2):560-65, 1987.	
CF	NAGATSU, et al., <u>Changes In Cytokines And Neotrophins In Parkinson's Disease</u> . J. Neural. Transm. Suppl. 60:277-290, 2000.	
CG	NOBLE, E. <u>Polymorphisms of The D2 Dopamine Receptor Gene and Alcoholism and Other Substance Use Disorders</u> . Alcohol. Supp. 2:35-43, 1994.	
CH	PORTER, et al., <u>Single Dose Comparison of Bicycladine, Codeine, and Placebo in Postoperative Pain</u> . Current Therapeutic Research. 30(3):156-160, August 1981.	
CI	SCATES, et al., <u>Reboxetine: A Selective Norepinephrine Reuptake Inhibitor For The Treatment Of Depression</u> . Ann. Pharmacother. 34(11):1302-12, 2000.	
CJ	SIMON, et al., <u>TCA's or SSRIs As Initial Therapy For Depression?</u> J. of Family Practice. 48:845-46, 1999.	
CK	SKOLNICK, et al., <u>"Broad Spectrum" Antidepressants: Is More Better For The Treatment of Depression?"</u> Life Sciences 73 (2003) 3175-3179	
CL	SKOLNICK, et al., <u>Antidepressant-like Actions of DOV 21,947: A "Triple" Reuptake Inhibitor</u> . Eur. J. Pharm. 461 (2003) 99-104	
CM	STACY, et al., <u>Treatment Options for Early Parkinson's Disease</u> . Am. Fam. Phys. 53:1281-87, 1996.	
CN	SULLIVAN, et al., <u>Mechanisms of Appetite Modulation By Drugs</u> , Federation Proceedings, Vol. 44, No. 1, Part 1, pp. 139-144, 1985.	
CO	WONG, et al., <u>Reboxetine: A Pharmacologically Potent, Selective, and Specific Norepinephrine Reuptake Inhibitor</u> . Biol. Psychiatry. 47(9):818-29, 2000.	
CP	SKOLNICK, P., <u>Beyond Monoamine-Based Therapies: Clues To New Approaches</u> . J. Clin Psychiatry 63:19-23, 2002.	
CQ	EPSTEIN, et al., <u>Bicycladine: Non-Narcotic Analgesic Activity of 1-ARYL-3-AZABICYCLO[3.1.0]HEXANES</u> . NIDA Res. Monogr. 41:93-98, 1982.	
CR	WANG, et al., <u>The Oral Analgesic Efficacy of Bicycladine Hydrochloride In Postoperative Pain</u> . J. Clin. Pharmacol. 22(4):160-164, April 1982.	



Examiner Signature		Date Considered	
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Sheet

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**NON PATENT LITERATURE DOCUMENTS**

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	BN	BALDESSARINI, R. <u>Drugs and The Treatment of Psychiatric Disorders</u> . Goodman & Gilman's The Pharmacological Basis of Therapeutics 9 <sup>th</sup> Edition. Hardman et al. eds. 1996. p. 399 and Ch 18:431-459, McGraw-Hill, New York	
	BO	BAYES, et al., Gateways to clinical trials - Allosteric Interaction Between The Site Labeled By [3H]mipramine And The Serotonin Transporter In Human Platelets. The oral analgesic activity of 1-aryl-3-azabicyclo[3.1.0]hexanes 1-aryl-3-azabicyclo[3.1.0]hexanes, a new series of non-narcotic analgesic agents. Methods Find Exp. Clin. Pharmacol. Apr Feb May 2003; 25(3):225-248.	
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